Notice of Allowability	Application No.	Applicant(s)	
	10/697,351	BUECHLER, KENNETH F.	
	Examiner	Art Unit	
	LYLE A. ALEXANDER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the 112/4/09 interview summary and Examiner's amendments*.

2. ☒ The allowed claim(s) is/are *1,5 and 8 renumbered 1-3 respectively*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *12/4/09* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Anavelys Ortiz-Suarez on 12/4/09.

Claim 1 has been amended:

1. A device for detecting one or more target ligands in a sample, comprising:
a nonporous surface comprising one or more particles immobilized to said surface,
wherein said particles comprise antibodies or fragments thereof immobilized to said particles,
wherein the antibodies or fragments thereof bind specifically to said one or more target ligands,
wherein said particle size range is from 1 nm to 5 μm, wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface, wherein one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface, and
wherein said assay device comprises a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface.

In claim 8 line 1 "claim 6" has been changed to –claim 1--.

Claim 4 has been canceled.

AMENDMENT TO SPECIFICATION:

Please delete the first paragraph of the specification and replace with the following paragraph:

This application is a continuation of US. Patent Application No. 09/613,650, ~~filed 07/11/2000~~ which issued as U.S. Patent No. 7,524,456 on 04/28/2009, which is a continuation-in-part of; U.S. Patent App. No. 08/828,041 which issued as Patent No. 6,156,270 on 12/05/2000, which is a continuation-in-part of U.S. Patent App. No. 08/447,895, which issued as U.S. Patent No. 6,019,944 on 02/01/2000, which is a divisional application of U.S. Patent App. No. 08/065,528 (abandoned), filed 05/19/1993, which was a continuation-in-part of U.S. Patent App. No. 07/887,526 which issued as Patent 5,458,852 on 10/17/1995; US. Patent App. No. 08/810,569 which issued as U.S. Patent No. 6,143,576 on 11/07/2000, which is a continuation-in-part of U.S. Patent App.

No. 08/447,981, which issued as U.S. Patent No. 5,885,527 on 03/23/1999, which is a divisional application of U.S. Patent App. No. 08/065,528 (abandoned), filed 05/19/1993, which was a continuation-in-part of U.S. Patent App. No. 07/887,526, filed 05/21/1992 which issued as Patent 5,458,852 on 10/17/1995; and U.S. Patent App. No. 08/902,775, which issued as U.S. Patent No. 6,271,040 on 08/07/2001, which is a continuation-in-part of US. Patent App. No. 08/828,041, now issued as Patent No. ~~6,019,944 on 02/01/2000~~ 6,156,270 on 12/05/2000, which is a continuation-in-part of both 08/447,981, which issued as U.S. Patent No. 5,885,527 on 03/23/1999, and 08/447,895, which issued as U.S. Patent No. 6,019,944 on 02/01/2000, both of which are divisionals of 08/065,528 (abandoned), which is a continuation-in-part of 07/887,526, which issued as U.S. Patent No. ~~4,458,852~~ 5,458,852 on 10/17/1995, from each of which priority is claimed, and each of which is fully incorporated by reference herein.

Please delete the Description of the Drawings section and replace it with the following Description of the Drawings section:

DESCRIPTION OF THE DRAWINGS

Figure 1 is a partially schematic, top perspective view of a device in accordance with the present invention.

Figure 1A is a partially schematic, perspective exploded view of the device showing the detail in the area of the sample addition reservoir, the sample-reaction barrier, the reaction chamber, the time gate and the beginning of the diagnostic element.

Figure 1B is a partially schematic, perspective exploded view of the device showing the detail in the area of the optional reagent reservoir, the sample addition reservoir, the sample-reaction barrier, the reaction chamber, the time gate and the beginning of the diagnostic element.

Figure 1C is a partially schematic, perspective exploded view of the device showing the detail in the area of the optional reagent reservoir in fluid contact with the sample addition reservoir and the reaction chamber.

Figure 1D is a partially schematic, perspective cutaway view of the flow control means.

Figure 2 is a partially schematic, perspective view of a second device in accordance with this present invention, which may be used to add pre-mixed reaction mixtures.

Figure 3A-B [[is]] are [[a]] partially schematic top views of the diagnostic element showing some potential placements of capture zones.

Figure 4 is a partially schematic, perspective view of a used reagent reservoir.

Figure 5 is a partially schematic view of embodiments of these devices which are columnar or have curved opposing surfaces.

Figure 6A-F [[is]] are top views of time gates.

Figure 7A-F show[[s]] typical dimensions for a preferred time gate.

Figure 8A-F [[is]] are top views of sequential time gates.

Figure 9A-D are views of preferred textured surfaces; as illustrated a textured surface can comprise texture structures which have curved or linear surfaces; the surfaces

can be smooth or uneven. Exemplary texture structures are conical (Fig. 9B-C), hexagons (Fig. 9D) or mounds (Fig. 9A). The structures depicted in Figure 9 are broadly considered posts.

Figure 10 depicts convex and concave flow fronts.

Figure 11 depicts a preferred embodiment of a device in accordance with the invention.

Figure 12A-F, respectively depict various embodiments of stops and energy directors in accordance with the invention; Figures 12A, 12C and 12E depict various embodiments without a lid attached; Figure 12B depicts an embodiment of Figure 12A with a lid attached, Figure 12D depicts an embodiment of Figure 12C with a lid attached, Figure 12F depicts an embodiment of Figure 12E with a lid attached. The energy directors and stops in Figure 12 can be configured as posts or ridges.

Figure 13 depicts a electron micrograph of an embodiment of the invention illustrating a sample addition reservoir 1, a textured sample reaction barrier 3, a textured reaction chamber 4, a textured used reagent reservoir 7, a stop 60, a point 70, and energy directors 62.

Figure 14 is an enlarged view of a portion of Fig. 13, illustrating textured sample reaction barrier 3, textured reaction chamber 4, an energy director 62, and stop 60.

Fig. 15 depicts an electron micrograph of an embodiment of the invention illustrating a time gate 5, a textured diagnostic lane 6, and an energy director 62.

Figure 16 A-B depict electron micrographs of two views of a textured surface adjacent an energy director 62. The energy director depicted in this embodiment has the form of a ridge.

2. The following is an examiner's statement of reasons for allowance: In addition to the remarks of record, the cite prior art fails to teach or suggest the claimed textured surface having depression and/or protrusions extending between 1 nm and 0.5 mm from the surface. Additionally, the cited prior art fails to teach or suggest the claimed particles entrapped within the depression and/or between the protrusions on the textured surface.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday though Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797